

Acknowledgement by the PTO of the receipt of applicant's papers filed under Section 119 is noted.

The commentary of the PTO with respect to applicant's election with traverse has been noted. With respect, applicant disagrees with part of the position of the PTO, maintains that such PTO position is incorrect and improper, and therefore maintains the previously stated traversal with respect to all claims which depend on claim 61. Applicant continues to maintain that PCT Rules 13.1. and 13.2 do not justify the position taken by the PTO, in that claim 61 clearly defines the same or corresponding special technical feature or features present in all the claims which depend from claim 61. Thus, it is clear that claim 61 covers all the groups, and this is even acknowledged by the breakdown on page 2 of the Restriction Requirement Office Action, Paper No. 10, mailed April 23, 2002.

In effect, by maintaining the restriction requirement, the PTO would be taking the position that applicant is not entitled under any conditions to a generic claim, e.g. claim 61 or some other generic claim, even if that claim meets all statutory requirements including those of §§102 and 103. This is clearly improper, and an action for which the PTO has no authority. If applicant's generic claim is patentable, just as in an election of species situation,

then applicant is entitled to all claims which fall within that genus, whether those claims are initially elected or initially non-elected.

To the extent that paragraph 2 on page 2 of the Office Action of August 13, 2002, corresponds to what is stated above, applicant acquiesces, and applicant accordingly has cancelled claims 93-96 and 101 without prejudice to applicant's rights.

Claim 91 has been objected to under Rule 75. The rejection is respectfully traversed.

Applicant respectfully notes that claim 90 recites the amount of beeswax as being "**about** 20% to about 50%". In the context of claims 90 and 91, it would be understood that 17% beeswax corresponds to "about 20%" of beeswax.

Nevertheless, in deference to the examiner's view, claim 90 has now been amended to delete "about 20% to about 50%". This should obviate the objection. Clearly, such amendment is not a "narrowing" amendment and does not introduce any limitations.

Withdrawal of the objection is respectfully requested.

Claims 73 and 86 have been rejected under the first paragraph of §112. This rejection is respectfully traversed.

The rejection states that the concentration (about 60%) of omega-3 as claimed in claims 73 and 86 is too high. This conclusion is based on US Patent No. 6,020,020 (Cain), which discloses (col. 1 lines 19-25) that "fish oils have significant health benefits. Above known oils however have one main, common disadvantage: i.e. either the total level of polyunsaturated fatty acids (such as: EPA, DHA, DPA, etc.) is rather low (i.e. below 35 wt % in total), or if this level is above 35 wt % its oxidative stability is low, while it also displayed high off-taste".

This information from Cain is not correct. There are in the market fish oils containing more than 35% omega-3. Cain also discloses that fish oils with a peroxide value above 6 are not edible, due to oxidation. Enclosed are copies of pamphlets from the Norwegian companies DENOFA and PRONOVA, well-known manufacturers of fish oil and the providers of the fish oil which may be used in the present invention, which show that the fish oil contains about 80% of omega-3 and has a rather low peroxide value (P.V.) (max 5meqO<sub>2</sub>/kg).

Withdrawal of the rejection is in order and is respectfully requested.

Claims 73, 77 and 84-92 have been rejected under the second paragraph of §112. This rejection is respectfully traversed.

As regards claims 73 and 77, applicant does not understand the basis of this rejection or even why this rejection is being made. Claim 73 does indeed recite the presence of omega-3 polyunsaturated fatty acids, but so do other claims which have not been rejected. Applicant does not accept that there is anything indefinite about the language "omega-3 polyunsaturated fatty acids".

If the rejection intends to suggest an inconsistency between claim 73 and claim 72 upon which it depends, then applicant must respectfully note that it should be well understood that the claimed composition can indeed comprise at least about 80% by weight of fish oil and still comprise only about 60% by weight of omega-3 polyunstaurated fatty acids, as fish oil is not 100% omega-3 polyunsaturated fatty acids.

Claim 77 does not even contain the language which is criticized, and therefore applicant does not understand why claim 77 has been rejected.

As regards claims 84-92, the word "suitable" has been deleted in deference to the examiner's views. This is clearly not a "narrowing" amendment; no limitations have been added and none are intended.

As regards claims 90 and 92, applicant respectfully disagrees with the rejection. No range within a range is recited; instead, the minimum of the range can run between

about 50% to about 80%, and there is nothing wrong with such a recitation. Applicant has not recited either "such as" or "preferably" or anything analogous. Nevertheless, a minor cosmetic amendment has been made in claim 90. Again, the amendment is not a "narrowing" amendment, and no limitations have been added.

With regard to claims 89-91, applicant respectfully notes that the term "solid paste" can indeed be found in the literature. Nevertheless, to avoid needless argument, the terminology now used is "semi-solid paste" which applicant intends to cover all pastes otherwise consistent with the language of the claims.

Applicant respectfully requests withdrawal of the rejection.

Claim 61-65, 68, 70-73, 78-81, 84-92 and 97-100 have been rejected as obvious from Cain et al USP 6,020,020 (Cain) in view of Grace GB 1,146,558 (Grace) further in view of Moskowitz USP 5,268,186 (Moskowitz), the Merck Index, and lastly alleged admissions of applicant at page 7, lines 20-26 and page 12, lines 1-11<sup>1</sup>. This rejection is respectfully traversed.

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<sup>1</sup> Applicant respectfully points out that the proposed combination of so many "references" together, by the very large number involved, itself suggests the non-obviousness of the present invention.

Cain describes a blend of triglycerides comprising (a) 0.3-95 wt % of a fish oil concentrate having a well-defined composition of 4 components, and (b) 99.7-0.3 wt % of a complementary fat, and food products made therefrom. The blend can be obtained by blending the individual triglycerides or by a sophisticated process that includes enzymatic and other steps, as described in Examples 1-3.

The results in Tables 1-3 show that the concentrates prepared by Cain's sophisticated process have improved properties such as lower peroxide values (PV) in comparison with the original fish oil. For example, Table 2.4 shows that the concentrate had a PV of 2.4 at room temperature (20 °C) after 3 weeks while the original fish oil had a PV of 8.5 at the same conditions. Cain mentions (col. 5, lines 3-6): "The samples were also analyzed for peroxide value (PV) as a measure of oxidative deterioration, a higher PV indicating a greater degree of oxidation".

Cain teaches the use of a fish oil concentrate that is processed from fish oil until it achieves the concentration defined in Cain's claim 1 and in Tables 1.1 and 1.2. As indicated above, the complementary fat is said to be present in the range of 0.3-95%. However, as far as it can be understood from the description and the examples, the amount of complementary fat defined in part (b) of Cain's claim 1 is

obtained by the blending of the individual triglycerides through the sophisticated process described on col. 2, lines 55-67, and col. 3, line 1, and in example 1, but not by mixing the liquid oil and the solid fat as in the present application.

Grace<sup>2</sup> describes a method for preparing a plastic low-fat content edible spread in which an edible wax, e.g. beeswax, is emulsified with an emulsifier such as glyceryl monooleate before addition to a fat, particularly hydrogenated fat, e.g. margarine or hydrogenated soybean oil, and a high amount of water (50 to 74 parts) is added thereafter to prepare a water-in-oil emulsion that is vigorously mixed and cooled to give a spreadable product.

The present invention describes a semi-solid or solid composition comprising at least 50% or more of at least one liquid oil, particularly fish oil, and 50% or less of at least one solid fat, particularly beeswax as called for in a number of applicant's claims.

The present claims thus call for a composition of matter that is semi-solid or solid at room temperature and is prepared by mixing at least one liquid oil (preferably fish

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<sup>2</sup> Grace was published in 1969, some thirty years before the priority date of the present application, and although fish oil was known to exhibit nutritional and other useful health properties, the present inventor was the first to suggest that it could be converted into a spread by mixing with beeswax. The spread according to the present invention was shown to be stable and to have a shelf-life of up to 24 months.

oil) with at least one solid fat (preferably beeswax). The invention is not obvious from the combination of Cain and Grace, because beeswax is not administered directly to oil in Grace, but only after addition of a high amount of water, and the fat is not administered directly to the oil in Cain.

Applicant does not see how Cain and Grace fit together. Cain teaches that the use of original oil from the fish is not advisable and provides a sophisticated process to obtain a product derived from original fish oil that has improved properties. Cain thus teaches away from using original oil fish for the blend. Grace teaches the dissolution of a mixture of beeswax with an emulsifier in the fat and addition of water to obtain a water-in-oil emulsion. Thus, Grace teaches away from preparing a composition comprising only the liquid oil and the solid fat without addition of water.

Applicant respectfully submits that the two references are not combinable with one another because they suggest different things which are not compatible, and therefore it would not have been obvious to the person of ordinary skill in the art to even attempt to combine these diverse citations. However, if one skilled in the art wished to attempt to combine these two diverse references, that skilled artisan would try to do what the two citations teach

is most important. With respect to Cain, it would be to not use original oil from the fish. With respect to Grace, it would be to add water. Therefore the only logical combination, if any combination at all were possible, it would be a composition containing water but not original fish oil. This would not correspond with the claimed subject matter.

Applicant submits, as regards those claims calling for beeswax, that it would not have been *prima facie* obvious to a person skilled in the art, at the time the claimed invention was made, to employ beeswax as supplementary fat to provide structural properties to a liquid oil such as fish oil. Please note that, according to the present invention, the beeswax is not added to Cain's fatblend, as stated in the rejection, but to the original fish oil that contains 20-90% (claim 63), preferably about 80% (new claim 102) of omega-3, and the composition contains about 60% of omega-3 (claim 73). The composition contains no water or emulsifier as taught by Grace.

Moskowitz (U.S. 5,268,186) describes the use of flavoring agents in food. If the basic composition is found to be patentable, the use of a flavorant, even if known, should be also patentable.

The rejection also appears to rely on alleged admissions at page 7, lines 20-26, and at page 12, lines 1-11

of applicant's specification. However, this makes no sense to applicant because the text in question relates to the present invention, not to the prior art. Thus, what appears at page 7, lines 20-26 is not any admission of any prior art, but instead is a description with respect to example 1 according to the present invention. The same is true with respect to the example 1 disclosure at page 12, lines 1-11.

Applicant respectfully requests withdrawal of the rejection based on §103.

The prior art documents of record and not relied upon have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicant's claims.

Favorable reconsideration and allowance are earnestly solicited.

Respectfully submitted,

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Version with Markings to Show Changes Made

63. (amended) A composition of matter according to Claim 62, wherein said at least one liquid oil ~~is in~~ the solidifying mixture contains from about 20% to about 90% by weight of omega-3 polyunsaturated fatty acids.

64. (amended) A composition of matter according to Claim 63, wherein said at least one liquid oil containing 20-90% omega-3 polyunsaturated fatty acids is fish oil.

65. (amended) A composition of matter according to Claim 64, wherein said fish oil contains ~~about 60%~~ above 50% by weight of omega-3 polyunsaturated fatty acids.

84. (amended) A homogenous semi-solid paste ~~suitable~~ for spreading comprising at least about 50% by weight of fish oil and about 50% or less of beeswax.

85. (amended) A homogenous semi-solid paste ~~suitable~~ for spreading according to Claim 84 comprising at least about 80% by weight of fish oil.

86. (amended) A homogenous semi-solid paste ~~suitable~~ for spreading according to Claim 85 comprising about 60% by weight of omega-3 polyunsaturated acids.

87. (amended) A homogenous semi-solid paste suitable for spreading according to Claim 85, further comprising at least one additional ingredient.

88. (amended) A homogenous semi-solid paste suitable for spreading according to Claim 87, wherein said at least one additional ingredient is selected from at least one odorant and at least one flavoring agent.

89. (amended) A method for the preparation of a composition of matter according to claim 61, the method comprising the steps of:

(a) heating a mixture of said at least one liquid oil and said at least one solid fat to a temperature above the melting point of said at least one solid fat, under conditions such that homogeneous consistency is obtained; and

(b) gradually cooling said mixture to room temperature, thus obtaining a homogeneous semi-solid ~~or solid~~ paste that can be stored at room temperature and/or by ~~household~~ refrigerating ~~by~~ ~~household means~~.

90. (amended) A method according to claim 89 for the preparation of homogeneous semi-solid paste suitable for spreading comprising from about at least 50% ~~to at least 80%~~

by weight of fish oil and ~~about 20% to about 50%~~ of beeswax,  
said method comprising the steps of:

- (a) mixing fish oil with beeswax at 80°C under stirring until a homogeneous consistency is obtained; and
- (b) cooling said mixture to room temperature, thus obtaining a homogeneous semi-solid ~~or solid~~ paste containing from at least about 50% to about at least 80% by weight of fish oil, that can be stored at room temperature and/or by household refrigeration ~~by household~~ means.

91. (amended) A method according to claim 90, for the preparation of homogeneous semi-solid paste suitable for spreading comprising about 83% by weight of fish oil, said method comprising the steps of:

- (a) mixing 400 g fish oil with 80 g beeswax at 80°C under stirring until a homogeneous consistency is obtained; and
- (b) cooling said mixture to room temperature, thus obtaining a homogeneous semi-solid ~~or solid~~ paste containing about 83% by weight of fish oil that can be stored at room temperature and/or by household refrigeration ~~by household~~ means.

92. (amended) A homogeneous semi-solid paste suitable for spreading comprising from about at least 50% to about at least 80% by weight of fish oil and from bout 20% to about 50% of beeswax, said homogeneous semi-solid paste being formed by a method comprising the steps of:

- (a) mixing fish oil with beeswax at 80°C under stirring until a homogeneous consistency is obtained; and
- (b) cooling said mixture to room temperature, thus obtaining said homogeneous semi-solid paste suitable for spreading.